

## DRUG FACTS BOX

# Exelon (rivastigmine)

## EXELON patch for mild-to-moderate dementia from Alzheimer's Disease

### What is the purpose of this box?

To explain the benefits and side effects of EXELON patch to help you decide whether to use this drug.

### What is this drug for?

To treat symptoms of dementia or mental decline due to mild-to-moderate Alzheimer's disease, which impairs people's ability to remember, learn, and reason. Like other dementia drugs, EXELON patch may temporarily improve symptoms, but it is not a cure.

### Who might consider taking it?

Adults with mild-to-moderate Alzheimer's Disease as indicated by a score of between 10 and 20 out of a possible 30 on the mini-mental status test of basic thinking skills (MMSE). An interactive version of the test is available at <http://tinyurl.com/maghexp>.

### Precautions to take

Be sure to remove old patch before applying new one. Do not apply multiple patches at same time. Patients and caregivers need to ensure adequate fluid intake because the drug can cause **dehydration** from not eating, or prolonged **vomiting** or **diarrhea**. Be alert for weight loss, bleeding in the stomach and intestines, worsening of symptoms of asthma or obstructive lung disease and fainting from a slow heart rate. Routinely evaluate the ability to continue driving or operating machinery. **EXELON PATCH CAN ALSO CAUSE OTHER UNCOMMON, LIFE-THREATENING OR SERIOUS SIDE EFFECTS:** A **very slow heart rate**, even in people with no prior heart problems, which could be potentially dangerous; **fainting** from too slow heart rate has been reported; **blockage** in the bladder making it difficult or impossible to urinate; **seizures**; **bleeding** in the stomach or intestines, especially people who have a history of ulcers or who are taking nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen (Advil, Motrin, and generic), or naproxen (Aleve and generic). **Movement disorders** called "extrapyramidal symptoms" such as tremor, slurred speech and severe restlessness; worsening of symptoms, particularly tremor, in patients with dementia from Parkinson's disease.

### What other choices are there?

Donepezil (ARICEPT 5 mg and 10 mg, and generic) and galatamine (RAZADYNE tablets, RAZADYNE extended release capsule, and generic). Monitored exercise therapy, occupational therapy, and activities that stimulate the brain such as art and music may also be helpful.

## BOTTOM LINE

### ■ EXELON patch's benefit

**Limited benefit in slowing deterioration of remembering, learning and reasoning**—Studies have consistently shown that, for the typical patient, Exelon slows deterioration in remembering, learning and reasoning **by only a modest amount**. The results for the Exelon capsule reported in this Drug Facts Box™ are essentially the same as those reported in recent high-quality systematic reviews of all trials testing the drug for dementia. [Cochrane Collaboration (2009), UK Health Technology Assessment Programme (2012), American College of Physicians (2008) and Drug Effectiveness Review Project (2006)]

**Never shown to improve quality of life, independent function or reduce institutionalization** No evidence that EXELON patch improves quality of life for either patients or caregivers, prolongs people's ability to function independently, or reduces the need for institutionalization—all major goals of treating dementia. Here's how the FDA's Medical Reviewer described the benefit of the Exelon patch [Overall Conclusion in the Executive Summary]:

*"The effect sizes were small and similar to those seen with the capsule formulation of Exelon® and with other acetylcholinesterase inhibitor drugs approved for the treatment of mild to moderate Alzheimer's Disease."*

### ■ EXELON's harm

**Can cause bothersome and potentially serious side effects**—EXELON can cause movement disorders, fainting, slow heart rate, diarrhea, nausea, vomiting, decreased appetite, and weight loss—all of which can be serious for older people with dementia. Nausea, vomiting and diarrhea are much less common with the patch than with the capsule.

**Shorter track record for patch means new, unexpected side effects are possible**—The FDA approved EXELON capsules in 2000 and the patch in 2007. Because the patch has not been widely used, important side effects may emerge when larger numbers of people—some with other conditions and on other medications—use the drug.

### ■ Comparing doses

The FDA approved patches of 4.6 mg to 13.3 mg daily. In a one-year study of people who worsened on 9.5 mg, those randomized to 13.3 mg tested better than those staying on 9.5mg on daily living activities, but not on remembering, learning or reasoning. To reduce the chance of side effects, start with the 4.6 mg patch for at least four weeks before increasing to the 9.5 mg (the lowest effective dose). Wait at least 4 weeks if increasing to the highest dose (13.3 mg). People with liver problems or who weigh less than 110 pounds may need to use the lower dose.

# Exelon Study Findings

The FDA approved the Exelon patch based on evidence from two randomized trials. The trial comparing the patch, capsule and placebo included 892 people with mild-to-moderate Alzheimer's Disease (average MMSE of 17) who were an average of 74 years old; about two thirds were women. Researchers randomly assigned participants to take the EXELON Patch, EXELON capsules, or a placebo (inactive sugar pill) **for about 6 months**. Here's what happened:

**EXELON PATCH** (9.5 mg once a day) **EXELON CAPSULE** (6 mg twice a day) **vs.** **Placebo** (No drug)

## How did EXELON help?\*

### Doctor's rating of change in dementia

Ratings of how dementia symptoms changed over six months were **about the same** for EXELON patch and capsules. For a few people, **EXELON helped more than a placebo**, but doctor's rated the majority of patients as unchanged or worse after six months.

#### Percent of people doctors rated as...

Markedly or moderately <b>improved</b>	14%	13%	vs.	9%
Minimally <b>improved</b>	17%	23%	vs.	20%
<b>Unchanged</b>	43%	38%	vs.	32%
Minimally <b>worse</b>	15%	12%	vs.	23%
Markedly or moderately <b>worse</b>	10%	14%	vs.	15%

### Remember, learn and reason

The typical person using EXELON scored slightly higher on a **71-point test** than those taking a placebo—**1.6 points better for those using the patch** and **1.6 points better for those using capsules**.

0.6 points **better** vs. 0.6 points **better** vs. 1.0 points **worse**

20 percent of people taking a placebo improved by the minimum noticeable amount (scores were better by 4 points or more). Compared to those taking a PLACEBO, **7 percent more of those using the EXELON Patch** and **9 percent more of those taking EXELON capsules** had the minimum noticeable improvement.

27% vs. 29% vs. 20%

### Ability to do daily living activities (for example, eating, getting dressed, or going to the bathroom)

All groups showed declines on a **54-point test**. Compared to those given a PLACEBO, the typical person using the EXELON PATCH scored **2.2 points higher** and the typical person using the EXELON capsules scored **1.8 points higher on the daily-activities test**.

0.1 points **worse** vs. 0.5 points **worse** vs. 2.3 points **worse**

## What were EXELON's side effects?\*\*\*

### Compared to those taking a PLACEBO:

2 percent more (patch) and 18 percent more (capsule) people had <b>nausea</b>	7%	23%	vs.	5%
3 percent more (patch) and 14 percent more (capsule) had <b>vomiting</b>	6%	17%	vs.	3%
2 percent more (patch) and 5 percent more (capsule) <b>lost weight</b>	8%	11%	vs.	6%
3 percent more (patch) and 2 percent more (capsule) had <b>diarrhea</b>	6%	5%	vs.	3%

\* Data from FDA Review Documents

\*\* Data from FDA-Approved Label

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